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510(k) Summary
Philips Model 453564036921
Prepared 8 January 2007

Owners' Name:
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1099

Contacts:

Contact Person:	**Alternate Contact:**
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Device Name:

Trade or Proprietary Name:	Motiva Monitor Device Connectivity
Common Name:	Telemedicine System
Classification Name:	Radiofrequency physiological signal transmitters and receivers (21 CFR 870.2910, Product Code DRG)

Legally Marketed Predicate Device:

Sponsor	**Predicate Device**	**510(k) Number**
BL Healthcare, Inc.	BL Management Remote Care Management System	K051470

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Device Description

Overview

The Motiva Monitor Device Connectivity (Motiva System) uses broadband and wireless technologies to create a link between the user and the user's Care Team. Information, such as educational videos, health surveys, and messages are sent to the user's television by way of a broadband connection. If the user has been supplied a Home Measurement Device, such as a Blood Pressure Monitor, Glucose Meter and Weight scale, readings are delivered to Motiva and retrievable by both the user and members of the user's Care Team. Based on the user's answers to assessment and stratification questions, The Motiva System enables the staff member to assign a Care Plan to the patient that provides a schedule for the delivery of educational materials, creates tasks for Care Team members when limits are exceeded, automates duties such as the delivery of reminders and motivational messages, and alerts Care Team members to users who may be at risk for not meeting care plan requirements.

How the device functions

A user interacts with the Motiva System by periodically (typically once or twice per day) using one or more measurement devices such as Blood Pressure Monitor, Glucose Meter or Weight Scale located in their home. These devices employ a wireless (Bluetooth) or wired link to communicate measurement data to an Internet Protocol Set Top Box, also located in the user's home. In turn, the Set Top Box communicates with the Medical Server (which includes Motiva Application software) using the user's broadband Internet connection. The information is sent to the healthcare professional's clinical client (containing Motiva Clinical Client software), which allows the healthcare professional to communicate back to the user in his/her home via the Internet to his or her own television set.

Scientific Concept

The scientific concept that forms the basis of the device are the telemonitoring studies that have shown that most persons with conditions such as Congestive Heart Failure (CHF) , Chronic Obstructive Pulmonary Disease (COPD), diabetes can safely and effectively monitor their conditions through telemonitoring.

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Significant Physical and Performance Characteristics

The Motiva System is a collection of off-the-shelf and custom designed Internet communication, audio / video interconnection devices and approved measuring devices and as such does not contain any significant physical or performance characteristics.

- The design of the device focuses largely on the software of the home and clinical user interfaces and is not significant.
- Materials used are largely standard off-the-shelf and slightly modified consumer electronic Internet communication and audio / video interconnection devices and as such the device's materials and physical properties are not significant.

Intended Use Statement

Motiva is used in non-clinical settings to support effective care management of in home patients, by collecting, documenting and transmitting historical health-related patient information. The Motiva Monitor Device Connectivity is used in conjunction with Motiva's Guide Service as a communication tool enabling healthcare providers the ability to remotely educate, motivate, and communicate with their patients, in combination with the ability to automatically collect in home patient parameter information derived from approved medical devices. Motiva is not intended to provide automated treatment decisions, nor is it to be used as a substitute for professional healthcare judgment. All patient medical diagnosis and treatment are to be performed under the direct supervision and oversight of an appropriate healthcare professional.

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Explanation of differences of Motiva System and Predicate Device Intended Use Statements

Underlined significant portions of Intended Uses are compared. The predicate device's Intended Use statement is reproduced in whole and in sequence paragraph by paragraph in the table below.

Predicate Device: BL Healthcare Remote Management system K051470	**Motiva Monitor Device Connectivity**	**Impact of differences to intended use of device and safety and effectiveness**
The purpose of the BL Healthcare Remote Care Management system is to collect and transmit medical information such as weight, blood pressure and pulse rate, and blood glucose from the patients on completion of their testing and transmit these results to their healthcare provider at another facility.	The Motiva Monitor Device Connectivity is used in conjunction with Motiva's Guide Service as a communication tool enabling healthcare providers the ability to remotely educate, motivate, and communicate with their patients, in combination with the ability to automatically collect in home patient parameter information derived from approved medical devices.	Same, no impact.
This system is installed by or with support from trained professionals.		Difference, Intended Use Statement does not address installation. No impact as the Motiva System is installed by trained professionals according to established installation procedures.

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Predicate Device: BL Healthcare Remote Management system K051470	Motiva Monitor Device Connectivity	Impact of differences to intended use of device and safety and effectiveness
This device is not intended to provide time sensitive data or alarms.	Motiva is not intended to provide automated treatment decisions, nor is it to be used as a substitute for professional healthcare judgment.	Difference, Intended use statement does not address data and alarms specifically. No impact as intent to not provide automatec decisions is the same.
This system may not be used as a substitute for direct medical intervention or emergency care.	Motiva is not intended to provide automated treatment decisions, nor is it to be used as a substitute for professional healthcare judgment.	Same, No Impact.
Interpretation of the information collected and transmitted requires clinical judgment by an experienced medical professional.	All patient medical diagnosis and treatment are to be performed under the direct supervision and oversight of an appropriate healthcare professional.	Same, No Impact.

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Technological Characteristics Summary
Differences are identified in the table below and are compared in the 2nd table.

Device **Technological Characteristic**	**BL Healthcare Remote Management system K051470**	**Motiva Monitor Device Connectivity**	**Difference**
Indications for use	Enable healthcare providers to manage chronic conditions of patients remotely	Enable healthcare providers to manage chronic conditions of patients remotely	Same
Intended use	Telemedicine system	Telemedicine system	Same
Intended users	Home users	Home users	Same
Site of use	Home; clinic	Home; clinic	Same
Data Collection Software	Proprietary Software	Proprietary Software	Same
Communication method with Remote Care Management System	Broadband Internet connection	Broadband Internet connection	Same
Types of sensors which can be interfaced (wired or wirelessly) to receiver hub	Blood Pressure Weight Glucose levels	Blood Pressure Weight Glucose levels	Same
Implementation method of collecting clearance by data from sensors	External communication device	Un-modified off-the-shelf 510(k) approved sensors	Difference 1
Sensor Software	Unchanged	Unchanged	Same
Connectivity	Wireless to hub	Wireless to hub	Same
Communication method of hub with devices	Wireless RF protocol	Bluetooth Serial Port Profile	Difference 2
Communications protocol	Proprietary	Bluetooth v1.2	Difference 3
Wireless frequency	915MHz FCC assigned channel	2.402 to 2.480 GHz (FHSS) ISM Band	Difference 4

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Device Technological Characteristic	BL Healthcare Remote Management system K051470	Motiva Monitor Device Connectivity	Difference
Power Source	Wall plug for hub (a/c) and batteries in devices	Wall plug for hub (a/c) and batteries for 510(k) approved sensor devices	Same
Display	On devices, hub, and monitors connected to Remote Care Management System	On 510(k) approved sensor devices and Television connected to Remote Care Management System	Same
Video conferencing	2 way video conference via a broadband internet connection	Not applicable	Difference 5
Medicine reminders	The system reminds the user to take medication if the information is programmed by the Healthcare Provider	The system reminds the user to take medication if the information is programmed by the Healthcare Provider	Same
Video User Training	Instructional video clips may be viewed by the user by selecting them from the menu if enabled by the Healthcare Provider	Health condition related educational videos may be viewed by the user by selecting them from the menu if enabled by the Healthcare Provider	Same
Care Plan Surveys	Not applicable	Care plan surveys may be completed if enabled by Healthcare Provider	Difference 6
Messages	Not applicable	Text messages may be sent between Healthcare Provider and patient to communicate various types of information	Difference 7

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Comparison of differences of technological characteristics between predicate device and submitted device.

Device Difference #	BL Healthcare Remote Management system K051470	Motiva Monitor Device Connectivity	How technological characteristics of submitted device compare to predicate device
1) Implementation method of collecting clearance by data from sensors	External communication device	Un-modified off-the-shelf 510(k) approved sensors	Similar but communication is more direct. No external communication device utilized. Approved measurement devices are utilized as-is with data transmitted from approved measurement devices to Set Top Box via Bluetooth Adapter or wired interface cable.
2) Communication method of hub with devices	Wireless RF protocol	Bluetooth Serial Port Profile	Very similar but non-proprietary, industry standard communication method is employed.

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Device Difference #	BL Healthcare Remote Management system K051470	Motiva Monitor Device Connectivity	How technological characteristics of submitted device compare to predicate device
3) Communications protocol	Proprietary	Bluetooth v1.2	Very similar but non-proprietary, industry standard communication method is employed.
4) Wireless frequency	915MHz FCC assigned channel	2.402 to 2.480 GHz (FHSS) ISM Band	Very similar but non-proprietary, industry standard communication method is employed.
5) Video conferencing	2 way video conference via a broadband internet connection	Not applicable	Similar, user to healthcare provider communications are accomplished with message capability and care plan responses.
6) Care Plan Surveys	Not applicable	Care plan surveys may be completed if enabled by Healthcare Provider	Responses to care plans serve as a form of communication similar to that which occurs with video conferencing.

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Device Difference #	BL Healthcare Remote Management system K051470	Motiva Monitor Device Connectivity	How technological characteristics of submitted device compare to predicate device
7) Messages	Not applicable	Text messages may be sent between Healthcare Provider and patient to communicate various types of information	Messages serve as a form of communication similar to that which occurs with video conferencing.

Non-clinical and clinical performance data.

Substantial equivalence is not based on non-clinical or clinical performance data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Philips Medical Systems
c/o Mr. Rick Schul
Senior Manager, Quality and Regulatory
3000 Minuteman Road
Andover, MA 01810-1099

Re: K071564
Trade/Device Name: Motiva Monitor Device Connectivity
Regulation Number: 21 CFR 870.2910
Regulation Name: Radiofrequency physiological signal transmitters and receivers
Regulatory Class: Class II
Product Code: DRG, DXN, FRW
Dated: June 7, 2007
Received: June 7, 2007

Dear Mr. Schul:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): To be assigned

Device Name: Motiva Monitor Device Connectivity

Indications for Use:

Motiva is used in non-clinical settings to support effective care management of in home patients, by collecting, documenting and transmitting historical health-related patient information.

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Prescription Use __**Yes**___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __**No**___ (21 CFR 801 Subpart C)

Rick Schul
Quality & Regulatory Manager
Philips Medical Systems

Date: May 17, 2007

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K071564